REMARKS

The final office action that was mailed on June 27, 2008, rejected claims 30-52. Applicants have amended independent claims 30 and 42 to more particularly define the subject matter sought to be patented, and have amended dependent claim 38 for consistency with independent claim 30. The amendments add no new matter and are fully supported by the original specification (e.g., at FIG. 3 and at paragraphs [0026] and [0027]). Claims 30-52 remain pending, and Applicants request reconsideration in view of the amendments above and the following remarks.

Finality of Office Action mailed June 27, 2008

Applicants filed a Request for Continued Examination (RCE) on May 19, 2008, along with an amendment submitted concurrently with the RCE. The amendment canceled, without prejudice, previously pending claims 1, 8, and 14-29 (which had been rejected in the final office action mailed April 19, 2007), and added new claims 30-52. The amendments added no new matter. The Examiner entered the amendment and withdrew finality of the previous office action.

However, despite Applicants' submission of the RCE and amendment with new claims 30-52, the Examiner issued the present final office action, contending that "[a]ll claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114." *See* Office Action, page 8.

Applicants submit that finality of the present office action is improper. As the Examiner notes, finality of a first office action following an RCE requires, among other things, that all claims are drawn to the same invention claimed prior to entry of the RCE. *See* MPEP 706.07(b). Several of the pending claims 30-52 recite subject matter not claimed prior to submission of the RCE, and thus cannot be considered "same invention" under MPEP 706.07(b). For example, Applicants submit that claim 31, which recites "wherein at least one of the electrodes is

positioned within the heart of the subject, and the sensed electrical activity waveform information is an electrogram signal," and claim 32, which recites "wherein at least one of the electrodes is positioned subcutaneously within the subject, and the sensed electrical activity waveform information is a subcutaneous electrocardiogram signal," do not meet the requirements for finality under MPEP 706.07(b) when considered against claimed subject matter prior to entry of the RCE. Additionally, claim 38 of the amendment, which recites "wherein the distal tip of the pressure transmission catheter is positioned within the subclavian artery," does not meet the requirements for finality under MPEP 706.07(b) when considered against claimed subject matter prior to entry of the RCE. For at least these reasons, finality of the office action of June 27, 2008 is improper and must be withdrawn under MPEP 706.07(d).

Accordingly, Applicants request withdrawal of the present final office action under MPEP 706.07(d).

Interview Summary

The undersigned thanks the Examiner for the courtesies extended during the telephone conversation of September 10, 2008, during which propriety of the present final office action was discussed. No agreement was reached.

With regard to the Examiner's summary, mailed October 10, 2008, of the above-mentioned telephone call, and specifically with regard to mention of claims 31 and 32, the undersigned offered claims 31 and 32 as examples of present claims that do not meet the "same invention" requirement for finality under MPEP 706.07(b) when compared to claims pending before the RCE. That is, the undersigned mentioned claims 31 and 32 as examples of why finality of the present office action under MPEP 706.07(b) is improper. Applicants do not concede that the Examiner's contentions regarding claims 31 and 32 are correct.

Claim Rejections – 35 U.S.C. § 103

Claims 30-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,937, 899 ("Sheldon") in view of U.S. Patent No. 4,846,191 ("Brockway '191").

Applicants have amended independent claim 30 to clarify that the "pressure sensing device [is] implanted so that a distal sensing tip of the pressure transmission catheter is

positioned within an artery accessible in a subcutaneous pectoral region of the chest but the transducer of the pressure sensing device remains outside of the artery." The amendment adds no new matter. Applicants submit that the 35 U.S.C. § 103 rejection of claim 30 is moot in view of the amendment above.

Claim 30 is patentable over Sheldon, Brockway '191, or their combination, because neither reference discloses or suggests a method that includes, among other things, "implanting within the subject a pressure sensing device comprising a pressure transmission catheter and a transducer in communication with the pressure transmission catheter, the pressure sensing device being implanted so that a distal sensing tip of the pressure transmission catheter is positioned within an artery accessible in a subcutaneous pectoral region of the chest, but the transducer of the pressure sensing device remains outside of the artery;" "receiving, within the implanted cardiac defibrillator, cardiac electrical activity waveform information sensed by the electrodes and pressure waveform information for the artery sensed by the implanted pressure sensor;" and "providing the cardiac therapy in the form of electrical defibrillation stimulation if the processing circuitry of the implanted cardiac defibrillator determines that an evaluation of both the cardiac electrical activity waveform information and the pressure waveform information shows there is occurring an aberrant rhythm for which therapy is appropriate."

Sheldon, by contrast, discloses a method of detecting ischemia in which a pressure signal is "obtained by a pressure transducer deployed within the heart or vasculature," and discloses that alternatively "the pressure sensor could be positioned around a blood vessel." (Column 2, lines 43-46; see also column 4, lines 57-64). Simply put, the approaches taught by Sheldon involve either monitoring endocardial pressure, monitoring pressure using a pressure transducer positioned within a heart chamber or vessel, or using a blood pressure cuff where the blood vessel is not penetrated. As such, the pressure sensors described by Sheldon are not, as recited in Applicants claim 30, "implanted so that a distal sensing tip of the pressure transmission catheter is positioned within an artery accessible in a subcutaneous pectoral region of the chest, but the transducer of the pressure sensing device remains outside of the artery." While Sheldon refers to blood pressure cuffs as described in U.S. Patent No. 6,077,227 to Meisel et al. (at column 4, line 63) to obtain a pressure signal from an artery for use in a therapy device, this method is

completely different from the method recited in claim 30, and is less effective for reasons described in Applicants' previous response.

Referring to arterial locations in rejecting claim 38, which recites the subclavian artery, the Examiner cited a section (col. 2, lines 43-46) of Sheldon that teaches "the pressure signal can be obtained from a pressure transducer deployed within the heart or vasculature." *See* Office Action, page 5. Claim 30 is clear that the transducer "remains outside of the artery." Also, the Examiner stated that "[g]iven the known use of the [subclavian] artery in defibrillation and pacing applications . . . those of ordinary skill in the art would have considered the use of the subclavian artery to be a matter of obvious design . . . ." *See* Office Action, page 5. Applicants respectfully disagree. Leads from pacemakers or defibrillators are routed into the heart through veins, not arteries. As Applicants' specification points out, "it is conventional to use a venous approach for . . . diagnostic and therapeutic devices." *See* paragraph [0026]. Sheldon offers no teaching, suggestion, or motivation for measuring a pressure from within an artery, and one of ordinary skill in the art would not be motivated to make such a measurement because of the traditional routing of leads into the heart in pacemaker and defibrillator applications. The claim 30 method that includes measuring pressure from an artery accessible in a subcutaneous pectoral region of the chest may not only avoid additional adverse impact on venous blood flow by omitting a pressure sense lead from the traditional defibrillation lead path, but may also obtain a better measure of cardiac function as compared to a measurement made from a venous location. *See* Applicants' specification, paragraph [0030]. Examples may include the subclavian artery, brachiocephalic artery, or the innominate artery.

Neither does Brockway '191 disclose or suggest implanting a pressure sensing device so that a distal sensing tip of the pressure transmission catheter is positioned within an artery accessible in a subcutaneous pectoral region of the chest. Further, Brockway '191 does not contemplate pressure sensing for use in providing electrical defibrillation stimulation, as recited in claim 30. Rather, Brockway '191 is described primarily for use in monitoring applications, and mainly for monitoring laboratory animals undergoing pharmaceutical drug testing. *See, e.g.*, column 1, lines 15-23; column 4, lines 18-38. In contrast to the pressure measurement site recited in claim 30, more easily accessible areas of a research animal, such as the renal artery, the

femoral artery, or the iliac artery, are typically used for the animal monitoring applications served by the devices described in Brockway '191.

Applicants' approach that is set forth in claim 30 provides a safe and effective means to obtain reliable pressure sensor information that can be used to determine, or confirm, that an electrical therapy should indeed be provided to the patient. It is also an approach that goes against conventional wisdom that it is not safe to leave a catheter in the artery of an ambulatory patient. However, Applicants' approach of providing only a small part of a pressure sensor – namely, the pressure transmission catheter – in an artery accessible in a subcutaneous pectoral region of the chest and using information from that sensor in a therapy device, is one that is neither disclosed, suggested, nor contemplated by the references of record. With Applicants' claimed subject matter, the smaller surface area of the sensor that is actually positioned within the artery makes the method safer, and there is less chance of thrombus developing. In addition, the pressure sensor is very light, and will therefore greatly reduce the risk of damaging the endothelial lining of the vessel, compared with other approaches that may be envisioned for measuring pressure using a sensor indwelling in the artery. Further, if the pressure transmission catheter were to accidentally pull out of the artery, given the small size of the portion of the sensor that extends into the artery (namely, the pressure transmission catheter), it is unlikely that any significant bleeding will result, a major safety concern with the use of other indwelling sensors used to monitor arterial pressure. As such, the approach set forth in Applicants' claim 30 provides significant advantages that are not disclosed or suggested by Sheldon or by Brockway '191.

For at least these reasons, claim 30 defines subject matter that is patentable over Sheldon, Brockway '191, or their combination, as do dependent claims 31-41. Separately, claim 38 is patentable over the references of record because the references fail to disclose or suggest measurement of pressure from the subclavian artery using the method set forth in claim 30.

Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of claims 30-41.

Independent claim 42, as amended, is similar to claim 30 and recites a system that is patentable over the references of record, as are dependent claims 43-52, for at least the reasons

discussed above with reference to claim 30. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of claims 42-52.

CONCLUSION

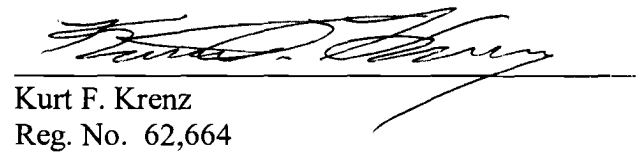
Applicants submit that each of claims 30-52 are in condition for allowance, and request that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please charge deposit account 06-1050 in the amount of $245 for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 26 Nov. 2008



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